

Janey E. Yorke Kanuy Eyorke

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Lowe, et al.

Serial No.: 09/762,794 - Case No.: 20276P

Art Unit:

1636

Filed:

March 23, 2001

Examiner: Guzo

For:

PROTEIN DELIVERY SYSTEM USING HUMAN

PAPILLOMAVIRUS VIRUS-LIKE PARTICLES

Assistant Commissioner for Patents Washington, DC 20231

DECLARATION UNDER 37 C.F.R. §1.131

Sir:

WILLIAM L. MCCLEMENTS hereby declares:

THAT, he is the William McClements named as co-applicant in United Stated Patent Application Serial No. 09/762,794, filed March 23, 2001, which is a national phase application under 35 U.S.C. § 371 of PCT application Serial No. PCT/US99/17931, filed August 10, 1999, which claims the benefit of U.S. provisional application 60/096,638, filed August 14, 1998;

THAT, he and the other named co-applicants constructed a nucleic acid encoding a fusion protein comprising a first segment comprising a nucleic acid encoding a portion of an

Ü.S.S.N: 09/762,794

Case No.: 20276P

Page No.: 2

HPV L2 protein which is less than a full-length sequence, and a second segment comprising a nucleic acid encoding a peptide or protein in the United States before February 20, 1998;

THAT, notebooks in my possession demonstrate the construction of the modified L2 gene, as exemplified in Example 1 of the Specification of United States Patent Application No. 09/762,794 (hereinafter the "Specification"). Copies of these notebook pages, attached as Exhibits A-E and H and specifically identified as below, show that the co-applicants designed and made PCR primers for the preparation of the modified L2 gene of HPV16, cloned said sequence, assembled the construct and validated that the construction was successful before February 20, 1998;

THAT, notebooks in my possession demonstrate the insertion and validation of an HPV E2 gene into the said vector, as exemplified in Example 2. Copies of these notebook pages, attached as Exhibits F and G and specifically identified as below, show that the co-applicants inserted a HPV16 E2 gene fused to L2 into the vector YP3#1 vector for expression in Saccharomycess cerevisiae, as exemplified in Example 3 before February 20, 1998;

THAT, all of the work reported on these notebook pages was either directly performed by one or more co-applicants or was carried out under the direction and control of the co-applicants;

THAT, Exhibit A is a true copy of Notebook No. 13856 pages 235-236 from the notebook of William McClements;

THAT, Exhibit B is a true copy of Notebook No. 16344 pages 19-20 from the notebook of Jessica Ling;

THAT, Exhibit C is a true copy of Notebook No. 16344 pages 257-258 from the notebook of Jessica Ling;

THAT, Exhibit D is a true copy of Notebook No. 16344 pages 233-234 from the notebook of Jessica Ling;

U.S.S.N: 09/762,794

Case No.: 20276P

Page No.: 3

THAT, Exhibit E is a true copy of Notebook No. 16344 pages 249-251 from the notebook of Jessica Ling;

THAT, Exhibit F is a true copy of Notebook No. 10038 pages 257-258 from the notebook of Michael Neeper;

THAT, Exhibit G is a true copy of Notebook No. 10038 pages 295-300 from the notebook of Michael Neeper;

THAT, Exhibit H is a true copy of Notebook No. 16344 page 271 from the notebook of Jessica Ling;

THAT, dates prior to February 20, 1998 on the Exhibits are blanked out in accordance with MPEP § 715.07;

The undersigned petitioner declares further that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

08 oct. 2002

Date

William I. McClements